METHOD OF USING A TISSUE CONTOURER

RELATED APPLICATIONS

[0001] This application claims priority from U.S. Provisional Patent Application Number 60/455,629, which was filed on March 18, 2003, and is entitled "Tissue Expander and Method of Using". This application is related to the co-pending application entitled "Oral Tissue Contourer" filed contemporaneously herewith, which is incorporated herein by reference for all that it teaches.

FIELD OF THE INVENTION

[0002] This invention relates generally to oral surgery. More particularly it relates to implantable oral devices and methods of using submucosal tissue expanders and contourers.

BACKGROUND OF THE INVENTION

[0003] The implantation of dental endosseous implants prosthetics or grafting material underneath mucosal or periosteal tissue is a common procedure performed both on the maxilla and the mandible. For these procedures to be surgically successful, the implanted or inserted material needs to be covered with vascularized mucosal tissue to aid in bone growth and to prevent infection. This covering of tissue is called primary closure.

[0004] When implant and bone grafts are not completely covered, the bone can lose volume or become infected especially in recent surgical sites. Collagen and other barriers have been used relatively recently to help in achieving primary closure, but there is still a loss of bone in these applications due to the lack of blood flow to the surgical sites.

[0005] Another problem associated with submucosal implantation is the extreme pressure exerted on the devices or materials that are implanted. Some researchers have attempted to rebuild or recontour eroded maxillary and mandibular ridges. The mucosal tissue is opened, the bone graft material inserted submucosally, and the mucosa is then sutured over the top. Unfortunately, the suturing stretches the tissue causing it, in turn to apply pressure on the bone graft material. The added pressure on the bone graft material can cause it to migrate away from the site of the implantation. The bone graft is never integrated completely. The primary reason for this failure is the lack of sufficient tension-free tissue to cover the graft material.

[0006] In some cases the bone graft material will merely migrate away from the graft site. In other cases, particularly where a rigid implant is inserted under the skin, the mucosal tissue may be impossible to suture. In other cases, the sutures may tear. In other cases, the mucosal tissue may erode and the implant may break though. All of these failures are due to the lack of sufficient tissue for the primary closure itself to cover the implant.

[0007] What is needed therefore is an improved process of preparing mucosal tissue for oral implants that provides sufficient mucosal tissue for the primary closure. What is also needed is an improved process of implanting that provides sufficient mucosal tissue to accommodate the implanted device or material. What is also needed is a process that will stimulate the patient's own body to generate and contour the tissue. What is also needed is a process for opening the generated tissue and inserting the implantables. What is also needed is a process for suturing the generated tissue after the implantables are inserted with sufficient space to prevent their migration. What is also needed is a method of expanding and contouring the vascularized mucosal tissue, so that when the underlying bone is rebuilt or otherwise restructured, it will completely cover the bone and a state of tension-free primary closure will be achieved.

[0008] It is an object of this invention to provide all of these in one or more claimed embodiments.

SUMMARY OF THE INVENTION

[0009] In view of the above, and in accordance with a first aspect of the invention, there is provided a method for implanting oral devices including the steps of making an incision in the oral cavity, inserting a tissue contourer in the incision; expanding the tissue contourer; removing the tissue contourer; and replacing the tissue contourer with an oral implant.

[0010] The method may include the step of making a second incision in the oral cavity prior to the step of removing the tissue contourer. It may also include the step of making the second incision in mucosal tissue overlying the tissue contourer. It may include the step of waiting for the incision to heal before expanding the tissue contourer. The step of replacing the tissue contourer with an endosseous implant may include the steps of replacing the tissue contourer with a dental endosseous implant, prosthetic, or grafting material.

[0011] These and other objects, advantages and aspects of the invention will become apparent from the following description. In the description, reference is made to the accompanying drawings which form a part hereof, and in which there is shown a preferred embodiment of the invention. Such embodiment does not necessarily represent the full scope of the invention and reference is made therefore to the claims herein for interpreting the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] **FIGURE1** is a facial view of an edentulous ridge that lies between two sets of teeth.

[0013] **FIGURE 2** is a top view of the ridge of **FIGURE 1**.

[0014] **FIGURE 3** is a facial view of the edentulous ridge in which tissue flaps have been pulled to either side of the crest of the bone.

[0015] **FIGURE 4** is a top view of the ridge depicted in **FIGURES 1-3**.

[0016] **FIGURE 5** illustrates a tissue contourer that has been inserted under the mucosal tissue with the tissue sutured over the contourer for primary closure.

[0017] **FIGURE 6** shows the first of a series of injections of sterile solution to inflate the tissue contourer after the sutured tissue has healed and the sutures have been removed.

[0018] **FIGURE 7** is a cross-sectional view of a first preferred placement of the tissue contourer as seen in section 6-6 of **FIGURE 6**. The contourer is illustrated in a location on the facial side of the edentulous ridge.

[0019] **FIGURE 8** is a cross-sectional view of a second preferred placement of the tissue contourer adjacent to the edentulous ridge as seen in section 6-6 of **FIGURE 6**. The contourer is illustrated in a location on the lingual side of the edentulous ridge.

[0020] **FIGURE 9** is a cross-sectional view of a third preferred placement of the contourer adjacent to the edentulous ridge as seen in section 6-6 of **FIGURE 6**. The contourer is illustrated in a location on the crest of the edentulous ridge

[0021] **FIGURE 10** is a cross-sectional view of a fourth preferred placement of the contourer disposed in a pronounced recess in the edentulous ridge as seen in section 6-6 of **FIGURE 6**. This illustrates a preferred placement when the ridge shows characteristics of uneven bone resorption.

[0022] **FIGURE 11** illustrates the tissue contourer as it is expanded by a subsequent injection to its final dimensions.

[0023] **FIGURE 12** illustrates the tissue contourer after it has inflated to its ultimate and preferred terminal volume prior to a second incision along the crest to remove it.

[0024] **FIGURE 13** shows a tissue contourer removal process in which the second incision has been made and the flaps formed thereby being reflected to either side of the crest of the edentulous ridge.

[0025] **FIGURES 14-16** illustrate an alternative process of oral tissue expansion. The illustrated process is an alternative to the steps shown in **FIGURES 1-5**, above.

[0026] **FIGURE 15** is a side view of the ridge of **FIGURE 14** showing the ridge after a tissue contourer insertion probe has been partially inserted into the incision illustrated in **FIGURE 14**.

[0027] **FIGURE 16** is a side view of the ridge of **FIGURES 14-15** showing the placement of a tissue contourer into the void formed by the probe of FIGURE 15.

[0028] **FIGURE 17** is a side view of a first preferred tissue contourer insertion probe in the form of a tube, the central portion of the tube being configured to carry a tissue contourer and a video device.

[0029] **FIGURE 18** is a side view of a second preferred tissue contourer insertion probe having two elongate members and a tissue contourer disposed therebetween.

[0030] **FIGURE 19** is a side view of a third preferred tissue contourer insertion probe coupled to one side of a tissue contourer and engaging the nose of the tissue contourer.

[0031] **FIGURE 20** is a side view of an orthoscopic camera that can be inserted into the void and used to inspect the bone of the edentulous ridge prior to the step of placing the tissue contourer into the void created by the probe.

[0032] **FIGURE 21** illustrates a first placement of a preferred tissue contourer in a completely edentulous ridge.

[0033] **FIGURE 22** shows a second placement of two tissue contourers in a completely edentulous ridge.

[0034] **FIGURE 23** is a detailed view of the two tissue contourers of **FIGURE 22** showing a preferred fluid coupling between the two.

[0035] **FIGURE 24** is a detailed cross-sectional view of the coupling of **FIGURE 23** showing the fluid fill tubes of the two tissue contourers coupled together by a T-coupling.

[0036] **FIGURE 25** shows an arrangement of three tissue contourers in a completely edentulous ridge using a T-coupling between two adjacent contourers and a single fill tube for the third contourer.

[0037] **FIGURE 26** shows a second arrangement of three tissue contourers in a completely edentulous ridge, each contourer having its separate and distinct fill tube.

[0038] **FIGURE 27** illustrates a step of removing periosteal tissue from the surface of bone on the edentulous ridge underneath tissue contoured by a previously removed tissue contourer.

[0039] **FIGURES 28-31** illustrate a process of attaching a block bone graft to the edentulous ridge after the tissue expander has been removed.

[0040] **FIGURES 32-35** illustrate a process of anchoring implants in the tissue after the tissue contourer has been removed.

[0041] **FIGURES 36-37** illustrate a process of fixing a structure such as a framework, mesh, or scaffolding to the edentulous ridge after the tissue contourer has been removed and filling the structure with bulk bone graft material after the tissue expander has been removed.

[0042] **FIGURES 38-43** illustrate a process of punching openings in tissue overlying a previously removed tissue contourer and inserting implants through those openings into the underlying edentulous ridge.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0043] While the present invention is susceptible to being embodied in various forms, the drawings show several preferred closure embodiments that will now be described. Please understand that the embodiments in this patent should be considered as just a handful of possible ways the invention might be embodied. They are provided here in sufficient detail for those skilled in the art of oral surgery to construct and perform. It is not intended to limit the invention to the specific embodiments described and illustrated here.

[0044] Referring now to the drawings, wherein like reference numerals refer to like parts throughout the several views, there is shown in **FIGURES 1-26** a method of using a tissue contourer in oral surgery that includes placing a tissue contourer into an incision adjacent to an edentulous ridge, expanding the tissue contourer to expand the mucosal tissue adjacent to the edentulous ridge, and removing the tissue contourer. **FIGURES 27-43** illustrate methods of fixing implants and bone grafts to the bone in the edentulous gap where the tissue contourer previously expanded the tissue.

[0045] In **FIGURE 1**, a side view of an edentulous gap **100** between two adjacent teeth **102**, **104** that define the ends of the gap. The gap **100** may be in any quadrant of the mouth: anterior, left posterior or right posterior. It may be either in the mandible or in the maxilla.

[0046] The gap **100** may be comprised of any number of missing teeth, including one tooth, all the teeth on a ridge (i.e. a completely edentulous ridge), or any number of teeth between one and all the teeth.

[0047] The gap may be entirely on one quadrant, it may extend across two adjacent quadrants, or it may extend across three adjacent quadrants.

[0048] A dashed line is shown in **FIGURE 1**, which represents an incision **106**. Incision **106** is made along the crest of the edentulous ridge **108**. The incision **106** does not terminate at the ends of the edentulous gap, but continues beyond the gap adjacent to the existing end gap teeth **102**, **104** which are disposed at opposing ends of the edentulous gap **100**.

[0049] The facial tail portions **112**, **114**, of incision **106** extend beyond the ends of the edentulous gap. They are provided to reduce the strain on the lingual edge **116** and facial edge **118** of the incision **106** when edges **116** and **118** are later sutured.

[0050] **FIGURE 2** is a top view of the edentulous gap after incision **106** has been made. Note that there are lingual tail portions **200**, **202** of the incision as well.

[0051] **FIGURE 3** illustrates the next step in the process: reflecting the incised mucosal tissue back to provide an opening to receive a tissue contourer or expander. In **FIGURE 3**, the edges of the incision have been separated and drawn apart to form two flaps, a lingual flap **300** and a facial flap **302**. These flaps are reflected, or drawn apart, to expose the top of the edentulous ridge. Depending upon the process used to form the incision, and the care taken to reflect the tissue, there may be a layer of periosteal tissue overlying the ridge. This layer is preferably manually removed to provide access to the underlying bone.

[0052] The periosteal tissue is preferably removed with a scraper or a powered burr, such as burr **304**. In one process the periosteal tissue alone is removed. In an alternative process, the periosteal tissue and the outer layers of bone are removed. Removing the periosteal tissue permits the contourer to be cemented or otherwise mechanically bonded to the edentulous ridge.

[0053] As shown in **FIGURE 4**, the lingual flap **300** is reflected toward the tongue and the facial flap **302** is reflected toward the face. In the preferred

embodiment, this reflection uncovers the entire ridge crest in the edentulous gap **100**.

[0054] **FIGURE 5** illustrates the step of inserting and securing the tissue expander or tissue contourer along the ridge in the edentulous gap **100**. This tissue expander or tissue contourer **500** preferably abuts teeth **102, 104.** These teeth define the ends of the gap **100**. The tissue contourer or expander is preferably any of the tissue contourers or expanders described in US Provisional Patent Application No. 60/455,629 or the co-pending patent application entitled "Oral Tissue Contourer", filed contemporaneously herewith, which are incorporated herein by reference for all that they teach.

[0055] The tissue contourer is oriented such that its longitudinal axis extends parallel to the ridge of edentulous gap **100** (the edentulous ridge) and it is lowered into contact with the crest of the ridge. Once in this position, the flaps that were previously reflected in **FIGURE 4** are drawn over the top of the tissue contourer **500** and are sutured together over the top of contourer **500** to enclose it. If the contourer **500** has an elongated port **502** that extends from the main body **501** of the contourer, the port **502** can be disposed to extend from underneath the sutured flaps, as shown in **FIGURE 5**. In other arrangements, to be discussed below, the port may extend from either end or from the middle of the body **501** of contourer **500**. Surgical cement or mechanical fasteners are used to attach the contourer **500** to the edentulous ridge to further prevent the contourer from moving relative to the maxilla or mandible.

[0056] Once in position with the flaps sutured across the top of the contourer, the sutured incision **106** is permitted to heal. The contourer is introduced into the incision when it is unexpanded, thereby permitting the incision to be sutured with little or no residual stress on the sutures in a tension-free primary closure. The incision heals relatively rapidly and without complications when the sutures are not stressed.

[0057] While the contourer **500** is preferably disposed along the crest of the edentulous ridge, it may be shifted to one side or another along the ridge crest to expand tissue in a preferred direction.

[0058] **FIGURE 6** shows the contourer **500** positioned along the crest of the edentulous ridge and extending the length of the edentulous gap that terminates with teeth **102** and **104**. In **FIGURE 6**, incision **106** has healed and the sutures have been removed. A needle, syringe or other device **602** is inserted into port **502** to fill, expand and contour the contourer by filling it with fluid.

[0059] While this is a preferred method for enlarging or expanding the contourer, any of the contourers pictured herein may be constructed in various manners to increase in volume by a variety of physical principles. It should be understood that the appearance of a port **502** in the accompanying **FIGURES** is not intended to limit the illustrated contourer **500** to one that is expanded by filling with fluid. Contourer **500** is shown in a position shifted more toward the facial side of the crest. This positioning causes the tissue to be contoured more toward the facial side of the eroded ridge, which in turn accommodates bone grafts that are also disposed more toward the facial side of the ridge.

[0060] **FIGURES 7-10** are alternative cross-sections of the edentulous ridge and the contourer **500** showing several alternative positions of the tissue contourer that are preferred alternative positions. Tooth **104** has been removed in each of these **FIGURES** for ease of illustration.

[0061] **FIGURE 7** shows the tissue contourer **500** disposed along the crest of the edentulous ridge and toward the facial side of the ridge. In this position the top **700** of the contourer **500** is adjacent to the crest **702** of the edentulous ridge.

[0062] **FIGURE 8** shows contourer **500** disposed along the crest of the edentulous ridge and toward the lingual side of the ridge. The top **700** of contourer **500** is adjacent to the crest **702** of the edentulous ridge.

[0063] **FIGURE 9** shows the tissue contourer positioned on the crest **702** of the edentulous ridge with the bottom **900** of the contourer **500** adjacent to and abutting the crest **702** of the edentulous ridge.

[0064] **FIGURE 10** shows the tissue contourer **500** disposed along the crest of the edentulous ridge and toward the facial side of the ridge and in a concave portion **1000** of the bone where facial bone is missing.

[0065] The next stage in the process is shown in **FIGURE 11**. Tissue contourer **500** is expanded over a period of time once the incision has healed. The method by which it is expanded depends upon the construction of the tissue contourer **500** itself. For example, if the tissue contourer **500** is a bladder, it can be filled manually by inserting a needle or other tool for inflation into the wall of the contourer body **501** or into the elongate port **502** extending from the contourer body **501** as shown in **FIGURE 11**. Tissue contourers using osmotic pressure as the mechanism for inflation, such as described in U.S. Patent No. 4,157,085, will self-inflate. Tissue contourers configured as mechanical stents can be periodically adjusted to increase their outside diameter. Tissue contourers may also employ tissue growth enhancers to grow and contour tissue. Alternative tissue expanders may use magnetic repulsion. They may incorporate bulk expansion materials such as cellulose, for example, to increase in size and contour tissue. They may incorporate screw tensioners to apply tension to tissue to be contoured or expanded. They may also incorporate other mechanical expansion devices.

[0066] Regardless of the method of expansion, the diameter of the contourer **500** is increased over a period of time, increasing the void in which the contourer is inserted. This gradual enlargement of the contourer **500** causes the outer surface of the mucosal tissue overlying the contourer **500** to gradually conform itself to the surface contours of the contourer, forming papillae where the contourer **500** has outwardly facing projections. Examples of these projections can be seen in the co-pending "Oral Tissue Contourer" application.

[0067] Once the contourer **500** has expanded and contoured the desired amount it is removed, as shown in **FIGURE 12**. **FIGURE 12** shows the contourer **500** as it would appear just before removal, with the overlying tissue contoured to match the surface of the contourer. In the preferred embodiment, the operator makes an incision **1200** in the mucosal tissue that generally follows the crest of the edentulous ridge. Once incision **1200** has been made, the two flaps **1300**, **1302** (**FIG. 13**) thereby created are reflected back from the incision **1200** and the contourer **500** is removed.

[0068] In the process above, a first incision was made into which the tissue contourer was inserted. This incision was then sutured and a time interval was provided for the incision to heal before the contourer **500** was expanded. As with any treatment is always desirable to reduce the amount of surgical trauma and enhance healing. This is best provided in the present application by avoiding the creating of the initial incision by creating a void beneath the mucosal tissue and inserting the contourer **500** into this void. This process is illustrated in **FIGURES 14-16**, and the surgical tools that may be used for this purpose are shown in **FIGURES 17-20**.

[0069] Referring to **FIGURES 14 and 15**, a short initial incision **1400** is made generally perpendicular to the length of the edentulous ridge. An elongated probe **1402**, such as one of those shown in **FIGURES 17-20** is inserted into this incision. The probe is forced through the incision and along the crest of the edentulous ridge creating a pocket or void that extends the entire length of the edentulous gap, from tooth **102** at one end of the gap to tooth **104** at the other end of the gap. The void **1500** (**FIG. 15**) thereby created preferably terminates adjacent to both of the teeth **102** and **104**.

[0070] Once void **1500** has been created, the probe is removed and the same (or another) probe is inserted in to the void. That probe or another probe may be inserted into the void a second time coupled to a contourer **500**, and dragging the contourer **500** into the void by pushing the leading end **1600** of

contourer **500** into a position adjacent tooth **104** at the closed end of the void. Examples of probes and expanders or contourers to which they are coupled may be found in the co-pending "Oral Tissue Contourer" application as well as in **FIGURES 17-20** herein. If contourer **500** has an elongated port extending from the body of the contourer, a portion of this port can be left outside the incision to permit the contourer to be filled. In the event the contourer does not have such a port, the entire contourer is preferably inserted into the void.

[0071] In the process and arrangement of **FIGURES 14-16**, the contourer can be immediately enlarged. Since there is no elongated incision such as incision **106** with sutures that can be torn loose, there is no need to wait for the incision to heal. The small incision **1400** through which the tissue contourer was inserted is preferably oriented perpendicular to the extent of the contourer and is preferably located at one end of the contourer. It therefore does not tend to tear open when the contourer is expanded.

[0072] **FIGURES 17-20** disclose several devices for making void **1500** and inserting contourer **500** into the void. In **FIGURE 17** a cannula **1700** is shown that has an elongated internal passage **1702** into which contourer **500** or an endoscope **2000** (**FIG. 20**) may be inserted. In a first process, the operator may insert the tip **1704** of cannula **1700** through incision **1400** and insert endoscope **2000** into the cannula. The operator views the mucosal tissue through endoscope **2000** and guides the cannula (and the endoscope it surrounds), cutting a surgical path through the tissue that defines void **1500**. In this manner, the operator creates a path that closely follows the contours of the edentulous ridge,

[0073] Once the void is formed, the operator inserts tissue contourer **500** into cannula **1700** and places it in the void, withdrawing the cannula from the void while ejecting the contourer from the end. Alternatively, the operator withdraws the cannula and inserts contourer **500** into the void.

[0074] **FIGURE 18** shows a forked insertion probe **1800** having two prongs **1802**, **1804** that extend from one end of probe **1800**. The operator places contourer **500** between these prongs to load the probe **1800** and inserts the loaded probe **1800** into void **1500** through incision **1400**. The operator manipulates the probe until the contourer **500** is in the proper position in the void, at which point the operator withdraws the probe **1800** leaving contourer **500** in place.

[0075] **FIGURE 19** shows a straight insertion probe **1900** engaged to an alternative contourer **500**. Probe **1900** is an elongate member having a distal end **1902** and a proximal end **1904**. Proximal end **1904** is configured to mate with and engage tip **1906** of contourer **500**. The operator inserts proximal eng **1904** into tip **1906**, thereby engaging the two. The operator grasps distal end **1902** and inserts proximal end **1904** together with tip **1906** into incision **1400**. By forcing probe **1900** forward into incision **1400**, the operator drags contourer **500** forward and into void **1500** by its tip **1906**, dragging the rest of contourer **500** behind the tip until the contourer is in the proper position in void **1500**.

[0076] **FIGURE 20** illustrates an endoscope **2000** for inspecting the void and for guiding the contourer into position. The endoscope includes an elongated barrel **2001**, having a knob **2002** at one end, the other end **2004** having a light-receiving opening **2006** configured to receive light. A light-carrying conduit **2008** extends laterally from the barrel to a remote image monitoring device (not shown) such as an electronic display, that receives and displays an image generated by the light gathered by the light-receiving opening **2006**.

[0077] In the foregoing embodiments, the contourer **500** is shown as a single elongated body filling the entire edentulous gap. Furthermore, the contourer body is shown as abutting the teeth adjacent the ends of the edentulous gap. Even further, the elongated port for filling the contourer is shown extending from one end of the contourer body. While these are the preferred forms and orientations

of contourer **500**, there are other forms and orientations that are suitable, such as those shown in **FIGURES 21-26**.

[0078] In **FIGURES 21-26** a totally edentulous ridge **2100** is shown. This ridge may be a maxillary or a mandibular ridge. It has no teeth that terminate the edentulous gap. In **FIGURE 21**, the first of these **FIGURES**, a single contourer **500A** is shown. This contourer has a central port **502A** and two ends **2104** and **2106**, each end disposed adjacent to the retromolar pads (if the contourer is in the mandible) or the tuberosity (if the contourer is disposed in the maxilla). The contourer may be placed in an incision (not shown in **FIGS. 21-26**) using the process shown in **FIGURES 1-11** or it may be inserted by a probe into a space using the process shown in **FIGURES 14-16**.

[0079] **FIGURE 22** illustrates an alternative contourer arrangement similar to that of **FIGURE 21**, but in the form of two contourers that are disposed adjacent to each other in an abutting relationship. These two contourers **500B**, **500C** are coupled to and are filled by a common port **502B**.

[0080] **FIGURE 23** illustrates the Y-tube **2300** of common port **502B** that joins the two contourers. **FIGURE 24** is a cross-sectional view of the Y-tube showing the check valve structure in the Y-tube **2300** that prevents fluid from escaping the contourers **500B, 500C**.

[0081] In **FIGURE 25**, an arrangement of three contourers **500, 500B, 500C** that are disposed end-to-end is shown. In this embodiment, two contourers **500B** and **500C** are coupled together to a common port **502B** by Y-tube **2300** for inflation and a third contourer **500** is placed adjacent to the end of contourer **500B** with its own port **502** for inflation.

[0082] In **FIGURE 26**, three tissue contourers **500** are disposed end-to-end are shown. Each contourer has its own port **502** which is provide for enlarging and expanding the contourer.

[0083] Thus, one, two or three tissue contourers may be disposed end-to-end in an edentulous gap, in which none, two or all are interconnected.

[0084] The foregoing **FIGURES** show the procedures involved in expanding and contouring mucosal tissue. Once the tissue is actually expanded and contoured, the process of inserting the implants or grafts is performed. These processes are illustrated in **FIGURES 27-43**. The processes of **FIGURES 27-31** illustrates how a block bone graft **2800** is fixed to the edentulous ridge.

[0085] In **FIGURE 27**, the tissue flaps **1300, 1302** formed when the tissue contourer is removed are reflected exposing the crest of the edentulous ridge. The periosteal tissue bonded to the crest of the ridge is then removed, preferably manually by a scraper or a burr **2702**. This process of removal may remove just the tissue, or more preferably the top layer of bone on the edentulous ridge; it may also contour the bone of the ridge to fit the bone graft. With the top layer of tissue and bone removed, a block graft **2800** is positioned on top of the edentulous ridge and is fixed in position with several fasteners, such as screws **2802**. As best shown in cross-section in **FIGURE 30**, the fasteners extend through the block graft and into the crest of the edentulous ridge. Once the block graft is fixed to the ridge, the two tissue flaps **1300, 1302** formed when tissue contourer **500** is removed are then drawn across the block graft **2800** and sutured, covering the graft.

[0086] In a second process, which may be performed subsequent to the graft of **FIGURES 27-31** or as an alternative to that process, one or more implants **3300** may be fixed to the ridge (either to the edentulous ridge itself, or the new ridge formed by the block graft of **FIGURES 27-31**) once the tissue contourer **500** is removed, as shown in **FIGURE 32-35**.

[0087] In **FIGURES 32-35**, the tissue flaps are reflected from the edentulous ridge (**FIGURE 33**) and holes **3200** are formed in the edentulous ridge (**FIG 32**). Implants **3300** are inserted into these holes and the flaps of tissue are drawn across the edentulous ridge and sutured together (**FIG. 35**), leaving the upper

portions **3302** of the implants exposed as shown in the facial view of **FIGURE 35**. The extra tissue formed by the contouring process can be gathered to form papillae such as the papillae **3304** shown in **FIGURE 35**.

[0088] In a third process shown in **FIGURES 36 and 37**, a framework, mesh, or scaffold **3600** such as any of the frames or scaffolds shown in patent 6,645,250, for example, may be fixed to the edentulous ridge when the tissue flaps **1300**, **1302** are reflected. The void between the framework or scaffold **3600** and the edentulous ridge is filled with bulk grafting material **3700**. When this bulk graft material integrates with the bone of the edentulous ridge, an implant such as those shown in **FIGURES 33-34** can be inserted.

[0089] In a fourth process shown in **FIGURES 38-43** a tissue punch **3900** is used to make openings in the tissue contoured by the tissue contourer **500**. In this process, however, the tissue contourer **500** is preferably not removed by making an elongated incision along the top of the edentulous ridge, but by extracting the tissue contourer from a narrow incision **3802** such as the incision through which the tissue contourer **500** was originally inserted into the void (see **FIGURES 15-16**). Alternatively, an elongate incision such as that shown in **FIGURES 12-13** can be made to remove the tissue expander, the incision sutured and permitted to heal before continuing with forming openings **3902**.

[0090] Once tissue contourer **500** is removed, an operator uses tissue punch **3900** to make one or more openings **3902** in the contoured tissue along the edentulous ridge. The tissue that is punched is removed, leaving generally circular or oval openings **3902** that are configured and located to receive implants (see **FIGS. 42-43**). The operator then inserts an explorer or periodontal probe **4002** through openings **3902** to lift the tissue away from the edentulous ridge. With the tissue lifted away from the ridge, a burr or other abrading device **4100** is inserted through the opening to remove periosteal tissue attached to the surface of the bone underneath the expanded tissue. The abrading device **4100** removes

the outer layer of periodontal tissue and the top layer of bone underneath the expanded tissue.

[0091] The operator then drills holes into the edentulous ridge where the openings **3902** are located, and anchors implants **4200** in those holes. The operator then inserts bulk bone graft material (not shown) underneath the tissue adjacent to implants **4200** with bulk bone graft material, thereby increasing the height of the mucosal tissue surrounding the implants **4200** and creating papillae **4300** between adjacent implants **4200**.

[0092] From the foregoing, it will be observed that numerous modifications and variations can be effected without departing from the true spirit and scope of the novel concept of the present invention. For example, the tissue contourer may be made in many different forms other than those illustrated herein. It may be an inflatable bladder. It maybe configured as a stent or otherwise expand by the release of stored mechanical pressure generated by flexible metal or plastic members. It may be self-expanding. It may expand by automatic inflation. It may fill under osmotic pressure.

[0093] The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims below.